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Robert L. Minier  
Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003

RE: Patent Term Extension  
Application for  
U.S. Patent No. 4,584,305  
Issued: April 22, 1986

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,584,305 issued April 22, 1986, which claims the human drug product Ergamisol, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be 423 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of October 19, 1990. Under 35 USC § 156(c):

Period of Extension =  $1/2$  (Testing Phase) + Approval Phase  
=  $1/2$  (1,290) + 230  
= 875 days

Since the regulatory review period began March 27, 1977, before the patent issued (April 22, 1986), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. 35 U.S.C. § 156(c). (From March 27, 1977, to April 22, 1986, is 3,313 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period:  $4,603 - 3,313 = 1,290$  days). No determination of a lack of due diligence under 35 USC § 156 (c)(1) was made.

The 14 year exception of 35 USC § 156(c)(3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (June 18, 1990) when added to the period of extension calculated above (875 days) cannot exceed 14 years. The period of extension is thus limited to June 18, 2004, by operation of 35 USC § 156(c)(3). Since the patent term of seventeen years (35 USC § 154) would expire on April 22, 2003, the period of extension is the number of days to extend the term of the patent from this time to June 18, 2004, or 423 days.

The limitations of 35 USC 156(g) (6) do not operate to reduce the period of extension determined above.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,584,305 a certificate of extension, under seal, for a period 423 days.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.	4,584,305
Granted:	April 22, 1986
Applicant:	Josephus Brugmans et al
Owner of Record:	Janssen Pharmaceutica N.V.
Title:	AIDING THE REGRESSION OF NEOPLASTIC DISEASE WITH 2,3,5,6-TETRAHYDRO-6- PHENYLIMIDAZO[2,1-b] THIAZOLE
Classification:	514/368
Product Trade Name	Ergamisol
Term Extended:	423 days

*C.E. Van Horn*

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Charles E. Van Horn  
Patent Policy and Programs Administrator  
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 11-44  
Rockville, MD 20857

RE: Ergamisol  
FDA Docket No. 90E-0266